CONFIDENTIAL

JUL 2 4 2002

TOWNLEY™ Transfacetpedicular Screw Fixation System
510(k) Summary
May 2002

K021705

page 1 of 1

I. **Company:**

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proprietary Trade Name:** TOWNLEY™ Transfacetpedicular Screw Fixation System

III. **Product Description:** The TOWNLEY™ Transfacetpedicular Screw Fixation System consists of screws designed to compress bone grafts. Both cortical and cancellous screw threads are available. The screws are fabricated from medical grade stainless steel described by such standards as ASTM F-138 or ISO 5832-1 or ISO 5832-9, or of titanium alloy described by such standards as ASTM F-136 or ISO 5832-3. The screws may or may not be used in conjunction with DYNALOK plates. When DYNALOK plates are used they are used to connect two or more screws together on one side of the spine at the base of the spinous process when the system is used for the second fixation method described below. Stainless steel and titanium implant components should never be used in the same construct. The sole purpose of this submission is to reduce the indications of the system.

IV. Indications: The TOWNLEY™ Transfacetpedicular Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods. The first fixation method uses the TOWNLEY™ Transfacetpedicular Screws as just facet fixation screws, where the screws are inserted bilaterally through the superior side of the facet, across the facet joint at (usually) a single level, and into the pedicle.

In the second fixation method, the TOWNLEY™ Transfacetpedicular Screws are inserted bilaterally through the superior side of the facet, across the facet joint, and into the pedicle at multiple levels at the same time that a DYNALOK® Plate is attached to the base of the spinous processes at the corresponding levels with TOWNLEY™ Transfacetpedicular Screws. The second fixation method should be used when the spine has increased instability or multiple levels need to be fused. Bone graft must be used for both fixation methods.

For both methods, this system is indicated for the posterior surgical treatment of any or all of the following at the C2 to T3 (inclusive) spinal levels: 1) Trauma, including spinal fractures and/or dislocations; 2) Spondylolisthesis; 3) Spondylolysis; 4) Pseudarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; 5) Degenerative diseases which include: (a) degenerative disc disease (ddd) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or; (b) degenerative disease of the facets with instability.

V. **Substantial Equivalence:** Documentation was provided which demonstrated the TOWNLEY™ Transfacetpedicular Screw Fixation System to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 4 2002

Richard W. Treharne, Ph.D.
Vice President Research and Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K021705
Trade/Device Name: TOWNLEY™ Transfacetpedicular Screw Fixation System
Regulatory Class: unclassified
Product Code: MRW
Dated: June 20, 2002
Received: June 25, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

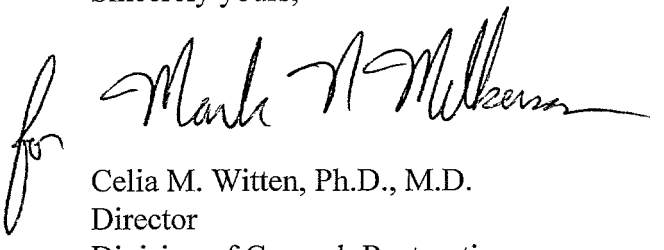
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

May 2002

510(k) Number (if known): K021705

Device Name: TOWNLEY™ Transfacetpedicular Screw Fixation System

Indications for Use:

The TOWNLEY™ Transfacetpedicular Screw Fixation System is intended to stabilize the spine as an aid to fusion by two different fixation methods. The first fixation method uses the TOWNLEY™ Transfacetpedicular Screws as just facet fixation screws, where the screws are inserted bilaterally through the superior side of the facet, across the facet joint at (usually) a single level, and into the pedicle.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021705

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